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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,809	07/08/2003	Qi Huang	A-817	1461
30174	7590	04/13/2006	EXAMINER	
AMGEN INC. 1120 VETERANS BOULEVARD SOUTH SAN FRANCISCO, CA 94080			KOSACK, JOSEPH R	
			ART UNIT	PAPER NUMBER
			1626	
DATE MAILED: 04/13/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/615,809	<b>Applicant(s)</b> HUANG ET AL.	
	<b>Examiner</b> Joseph Kosack	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 13-15, 20-22, 28, 31, 33, 35 and 37-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 16, 17, 19, 23-27, 29, 30, 32, 34 and 36 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/3/03, 2/3/04, 7/27/05</u> | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1-45 are pending in the instant application.

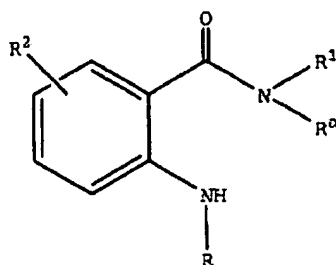
#### *Election/Restrictions*

Applicant's election without traverse of Group I, claims 1-36 along with an election of species in the reply filed on February 27, 2006 is acknowledged.

#### *Status of the Claims*

Claims 1-45 are pending in the instant application. Claims 1-12 (in part), Claims 13-15, Claims 16-19 (in part), Claims 20-22, Claims 23-27 (in part), Claim 28, Claims 29-30 (in part), Claim 31, Claim 32 (in part), Claim 33, Claim 34 (in part), Claim 35, Claim 36 (in part), and Claims 37-45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in the structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

Pursuant to Applicant's election of a species, the scope of the invention will be limited to the following substitutions of the base structure



where:

- R is  $-(CH_2)_1-R^3$ ;

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- R<sup>3</sup> is a 6 membered ring with ring members consisting of only carbon and nitrogen, optionally substituted as defined, optionally unsaturated as defined;
- All other substituents are as defined;

As a result of the election and the corresponding scope of the invention defined supra, the remaining subject matter of Claims 1-12, 16-19, 23-27, 29-30, 32, 34, and 36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions. The withdrawn compounds contain varying functional groups such as pyrimidinyl, piperidinyl, imidazolyl, pyrrolidinyl, etc, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e. class 544 subclass 244(+) (diazines), class 546 subclass 184(+) (piperidines), 546 subclass 249(+) (pyridines), etc. Therefore the subject matter which are withdrawn from consideration as being non-elected subject matter differ materially in structure and composition and have been restricted properly a reference which anticipated but the elected subject matter would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

#### ***Priority***

The claim to priority of US Serial No. 60/395,144 filed on July 9, 2002 has been acknowledged in the instant application.

#### ***Information Disclosure Statement***

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The Information Disclosure Statements filed on November 3, 2003; February 3, 2004; and July 27, 2005 have been considered fully by the Examiner.

### ***Claim Objections***

Claims 1-12, 16-19, 23-27, 29-30, 32, 34, and 36 are objected to for containing elected and non-elected subject matter. The elected subject matter have been identified supra.

### ***Claim Rejections - 35 USC § 102***

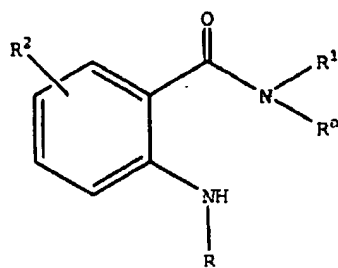
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 rejected under 35 U.S.C. 102(b) as being anticipated by Lockemann et al. (*Chemische Berichte* 1947, 485-493).

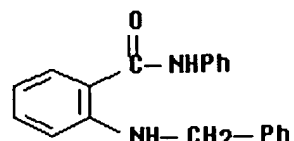
The instant application cites compounds of Formula I,



where: R is  $-(CH_2)_1-R^3$ ; R<sup>3</sup> is a 6 membered ring with ring

members consisting of only carbon and nitrogen, optionally substituted as defined, optionally unsaturated as defined; and all other substituents are as defined.

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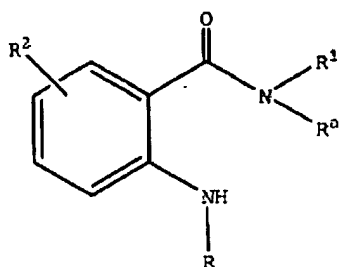
Lockemann et al. teach a compound of the formula:

reads on the instant claims when R is  $-(CH_2)_1-R^3$ ,  $R^1$  and  $R^3$  are phenyl, and  $R^a$  and  $R^2$  are hydrogen. See page 490, Section V-3.

Claims 1-2, 8, 10-12, 16-17, 19, 23-25, 29, and 36 rejected under 35 U.S.C.

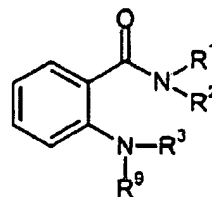
102(b) as being anticipated by Huth et al. (WO 00/27819).

The instant application cites compounds of Formula I,



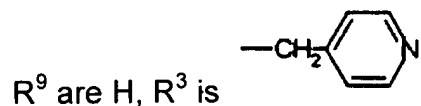
where: R is  $-(CH_2)_1-R^3$ ;  $R^3$  is a 6 membered ring with ring

members consisting of only carbon and nitrogen, optionally substituted as defined, optionally unsaturated as defined; and all other substituents are as defined.



Huth et al. teach a compound with the formula:

where  $R^2$  and



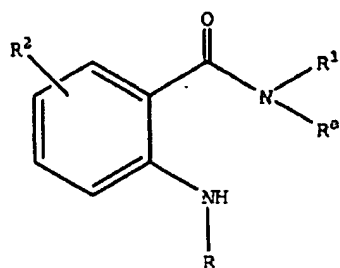
$R^9$  are H,  $R^3$  is , and  $R^1$  is 3-pyridyl, which reads on the instant claims

when R is  $-(CH_2)_1-R^3$ ,  $R^1$  and  $R^3$  are pyridyl, and  $R^a$  and  $R^2$  are hydrogen. See

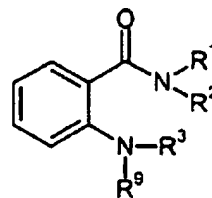
Example 2.40 on page 44.

Claims 1-4, 10-12, 16-17, 19, 23-25, 29, and 36 rejected under 35 U.S.C. 102(b) as being anticipated by Huth et al. (WO 00/27819).

The instant application cites compounds of Formula I,

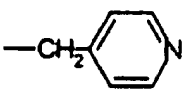


where:  $R$  is  $-(CH_2)_1-R^3$ ;  $R^3$  is a 6 membered ring with ring members consisting of only carbon and nitrogen, optionally substituted as defined, optionally unsaturated as defined; and all other substituents are as defined.



Huth et al. teach a compound with the formula:

where  $R^2$  and

$R^9$  are H,  $R^3$  is , and  $R^1$  is 7-1,2,3,4-tetrahydroquinolyl, which reads on the instant claims when  $R$  is  $-(CH_2)_1-R^3$ ,  $R^3$  is pyridyl,  $R^1$  is a 1,2,3,4-tetrahydroquinolyl and  $R^a$  and  $R^2$  are hydrogen. See Example 2.49 on page 45.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

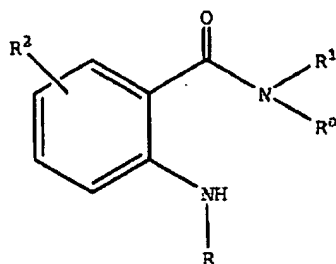
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12, 16-17, 19, 23-25, 29-30, 32, 34, and 36 rejected under 35 U.S.C. 103(a) as being unpatentable over Altmann et al. (USPN 6,448,277).

The instant application cites compounds of Formula I,



where: R is  $-(CH_2)_1-R^3$ ; R<sup>3</sup> is a 6 membered ring with ring

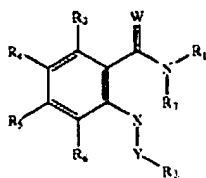


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members consisting of only carbon and nitrogen, optionally substituted as defined, optionally unsaturated as defined; and all other substituents are as defined.

Determination of the scope and content of the prior art (MPEP §2141.01)

Altmann et al. teach compounds and compositions of Formula I:



with substituents as defined. See column 2, line 43, through column 3,

line 12 and column 25, lines 23-33.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Altmann et al. do not teach specifically all of the compounds which fall into the scope of the instant invention.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Altmann et al. teaches generally compounds of the instant invention when W is O, X is NR<sub>8</sub>, Y is CR<sub>9</sub>R<sub>10</sub>-(CH<sub>2</sub>)<sub>n</sub>, R<sub>1</sub> is aryl, R<sub>2</sub> is a 6-membered heteroaryl ring comprising one ring nitrogen, and R<sub>3</sub> through R<sub>10</sub> are hydrogen. See column 2, line 43 through column 3, line 12.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to follow the synthetic scheme of Altmann et al. to make the claimed invention with a reasonable expectation of success. The motivation to do so is provided by Altmann et al. Altmann et al. teaches the use of the synthesized compounds to treat arthritis. See column 9, lines 59-62.

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Thus, the claimed invention as a whole was *prima facie* obviousness over the combined teachings of the prior art.

### ***Double Patenting***

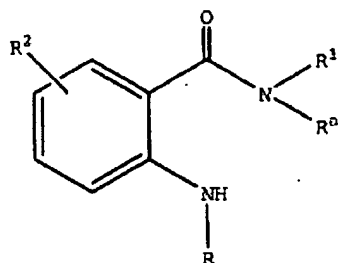
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12, 16-17, 19, 23-25, 29-30, 32, 34, and 36 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 6,448,277.

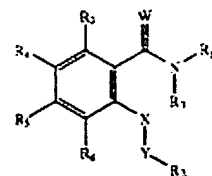
The instant application cites compounds of Formula I,



where: R is  $-(CH_2)_1-R^3$ ; R<sup>3</sup> is a 6 membered ring with ring

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members consisting of only carbon and nitrogen, optionally substituted as defined, optionally unsaturated as defined; and all other substituents are as defined.



'277 teaches compounds and compositions of Formula I:

with

substituents as defined.

'277 does not teach specifically all of the compounds which fall into the scope of the instant invention.

'277 teaches generally compounds of the instant invention when W is O, X is  $\text{NR}_8$ , Y is  $\text{CR}_9\text{R}_{10}-(\text{CH}_2)_n$ ,  $\text{R}_1$  is aryl,  $\text{R}_2$  is a 6-membered heteroaryl ring comprising one ring nitrogen, and  $\text{R}_3$  through  $\text{R}_{10}$  are hydrogen.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to follow the synthetic scheme of '277 to make the claimed invention with a reasonable expectation of success. The motivation to do so is provided by '277 '277 teaches the use of the synthesized compounds to treat arthritis. See column 9, lines 59-62.

Thus, the claimed invention as a whole was *prima facie* obviousness over the combined teachings of the prior art.

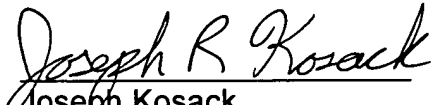
### Conclusion

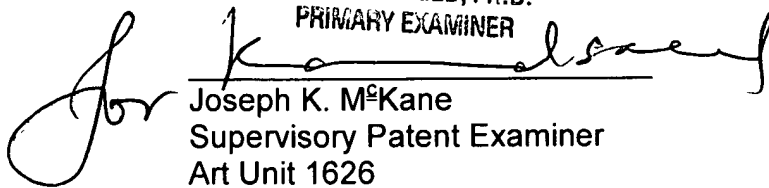
Claims 1-12, 16-17, 19, 23-27, 29-30, 32, 34, and 36 are rejected. Claims 1-12, 16-19, 23-27, 29-30, 32, 34, and 36 are objected to. Claim 18 is free of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-5575. The examiner can normally be reached on M-F 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>c</sup>Kane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Joseph Kosack  
Patent Examiner  
Art Unit 1626

  
KAMALA A. SAEED, PH.D.  
PRIMARY EXAMINER  
Joseph K. M<sup>c</sup>Kane  
Supervisory Patent Examiner  
Art Unit 1626